

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor : DALEY  
Appln. No. : 09/670,781  
Conf. No.: 6751  
Filed: September 27, 2000  
Title: SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTION

Group Art Unit : 1761  
Examiner : WEINSTEIN, S.  
Docket No. : PH 011149US1

\* \* \* \* \*

June 14, 2010

**REQUEST FOR REHEARING UNDER 37 CFR § 41.52**

MS Appeal Brief Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

Pursuant to 37 CFR § 41.52, Appellant respectfully requests rehearing of Appellant's appeal in the above captioned application. This request is being timely filed within two months of the April 28, 2010 Decision On Appeal ("Board's Decision"). *See* 37 CFR 41.52(a)(1).

Appellant requests rehearing because the Board's Decision misapprehended three points made in Appellant's opening brief and/or reply brief.

**I. The Board's Decision Misapprehended The Significance Of Lazure's "Unit Dose" Teaching**

All pending rejections are based on the Office Action's assertion that because (1) "the application of a single serve or single use cups for all type of products, edible, medicinal and inedible, in all sizes and shapes of cups, is notoriously conventional in the art of packaging" (*see, e.g.*, Lazure, Hendriks, Beckers), and (2) "sugar solutions have been formulated to use as a pain relief/calming medium for infants" (*see, e.g.*, Blass, Stevens 1999, Stevens 1997, Frank), it

would have been obvious to use such single cups to store medicinal sugar solutions, and that such a modification would result in the combination of recitations in the claims. 7/13/05 Office Action, pp. 2-3; 3/13/02 Office Action, p. 3.

Page 8 of Appellant's March 20, 2009 Appeal Brief explained that Lazure (U.S. Patent No. 4,054,207) teaches the use of precisely measured "unit doses of medicine" in a container. *See Lazure*, col. 1, lines 5-6. Those of ordinary skill in the art would have understood that the purpose of such "unit dose" containers of medicine is to avoid overdosing or underdosing that would result from including more or less than a unit dose of medicine in the container. Lazure's "unit dose" teaching would have therefore discouraged those of ordinary skill in the art from including more than a unit dose of medicinal sucrose solution in Lazure's container because doing so might result in overdosing. *See* Appellant's 3/20/09 Brief, p. 9.

The Board's Decision disregarded Lazure's "unit dose" teaching because "Appellant has not explained why Lazure's disclosure should be construed as limited to containers of a size too large to accommodate a unit dose or sucrose solution." Board Decision, p. 8. However, the significance of Lazure's "unit dose" teaching has nothing to do with the size of Lazure's container. Rather, Lazure's "unit dose" teaching is significant because it would discourage those of ordinary skill in the art from including more than a "unit dose" of sucrose solution in Lazure's container, regardless of the size of Lazure's container.

The Board's Decision also disregarded Lazure's "unit dose" teaching because "Appellant has not identified, nor do we find, any disclosure which supports Appellant's contention that Lazure 'critically focuses on administering the entire contents of the unit dose container.'" Board's Decision, p. 9 (quoting Appellant's Reply Brief, p. 10). Appellant submits that the Board misapprehended the purpose of Lazure's "unit dose" teaching. As explained above, those of ordinary skill in the art would understand that the purpose of a "unit dose" of medicine is to avoid the dangers that might accompany overdosing or underdosing. This is particularly relevant here because the prior art proposed to be combined with Lazure relates to medicinal sucrose solutions (*see, e.g.*, Blass, Stevens 1999, Stevens 1997, Frank). If one of ordinary skill in the art were to place such medicinal sucrose solutions into Lazure's container, then such an artisan would have applied Lazure's "unit dose" medicine teaching, because Lazure discourages (i.e., teaches away from) including more than a unit dose of medicine in Lazure's container. *See* Appellant's 3/20/09 Brief, p. 9.

Here, as explained in Appellant's opening brief, placing such a "unit dose" of the prior art sucrose solution into Lazure's container would have made it impossible to administer the whole unit dose. *See* Appellant's 3/20/09 Brief, p. 9. The asserted sucrose solution references teach that only a very small dose of sucrose solution (e.g., from 0.05 to 2 ml) is ever administered to a newborn patient. *See, e.g.*, Franck, p. 1 ("Two milliliters of 24% sucrose solution....;" "smaller doses of sucrose (as little as 0.05 ml)"); *see also id.* at p. 2 ("Only a very small drop (less than .05 ml) of the sucrose solution administered by syringe, dropper, or pacifier is needed."). Because an appropriate unit dose of sucrose solution is so small, if it were placed in Lazure's container, it would be difficult or impossible to administer the entire unit dose to a patient. *See* 3/20/09 Brief, p. 9. For example, it would be difficult or impossible to transfer the entire unit dose from in the container to a pacifier for subsequent administration to a patient, particularly in view of how small a unit dose of such a sucrose solution is. *See id.* Thus, the proposed combination would prevent or seriously impair a physician's ability to administer a full unit dose of sucrose solution to a patient, as is emphasized by Lazure's "unit dose" teaching. Such an underdosing result would entirely defeat the purpose of "unit dose" teachings such as Lazure. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Moreover, the resulting additional hassle associated with attempting to administer the entire contents of the container are antithetical to the convenience goal of Lazure's "unit dose" container.

To the extent that the pending rejections are based on the assertion that it would have been obvious to fill Lazure's container with more than a unit dose (Appellant disputes the obviousness of this), the resulting combination would no longer contain a unit dose of medicine. Such a result is again antithetical to Lazure's "unit dose" teaching because it defeats the exact unit dose goal of Lazure, and could result in the overdosing that Lazure's "unit dose" container seeks to prevent. *See* Appellant's 3/20/09 Brief, p. 9; *see also* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Put another way, the proposed combination is nonobvious because it would change Lazure's principle of operation, i.e., the use of a "unit dose" container to ensure the convenient administration of a correct dose of medication. *See* MPEP 2143.01(VI) ("If the proposed modification or

combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”).

Appellant submits that the Board’s Decision misapprehended the significance of Lazure’s “unit dose” teaching, which teaches away from the proposed combination of prior art. Appellant therefore respectfully request the reversal of the pending rejections, all of which rely on the non-obvious combination of Lazure and medicinal sucrose solution prior art.

## **II. The Board’s Decision Overlooked Appellant’s Proof That An Adulatory Competitor’s Product Reads On Appellant’s Claims**

As explained on pages 14-15 of Appellant’s March 20, 2009 Brief and supporting evidence, Appellant’s direct competitor, Hawaii Medical, LLC, prominently advertises and promotes the presently claimed invention through its advertisement for its TootSweet product (Evidence Exhibit D to Appellant’s 3/20/09 Brief). *See* 3/20/09 Appeal Brief at 14-15. Such adulation for the presently claimed invention clearly demonstrates that even Appellant’s competitor recognized the uniqueness, marketability, and value of the presently claimed invention. Such adulation by an unbiased and independent third party is “a strong indication of the non-obviousness of [the] invention.” *Libbey-Owens-Ford Co. v. BOC Group Inc.*, 655 F. Supp. 897, 914, 4 USPQ.2d (BNA) 1097, 1109 (D. N.J. 1987) (“[S]tatements of praise by the [accused infringer] made prior to the initiation of litigation are a strong indication of the non-obviousness of [the] invention.”); *see also Gambio Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ.2d (BNA) 1378, 1384 (Fed. Cir. 1997) (holding that an infringer’s “recognition of the importance of [the patented invention] is relevant to a determination of nonobviousness”); *Minnesota Mining & Manufacturing v. Smith & Nephew PLC*, 25 USPQ.2d (BNA) 1587, 1592 (D. Minn. 1992) (“Insofar as [the accused infringer’s marketing] information lends insight into a defendant’s actual beliefs about the relative uniqueness, superiority and marketability of a disputed patent, it has been recognized as valuable in evaluating a defendant’s public assertions that a patent was obvious and therefore invalid.”).

The Board’s Decision disregarded Hawaii Medical’s adulation for the claimed invention on the ground that “Appellant has not directed us to any evidence which establishes that Appellant’s claims read on the advertised product.” Board’s Decision, p. 14. To the contrary,

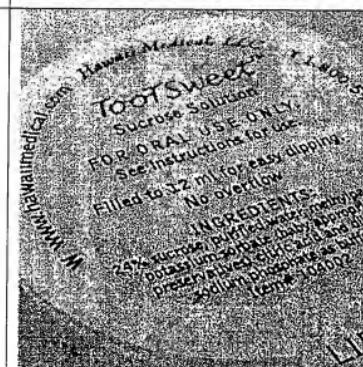
Appellant's March 20, 2009 Brief explained that "[a]s the [Hawaii Medical] advertisement [attached as Evidence Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief] clearly shows, independent claims 1, 23, and 29 clearly cover [Hawaii Medical's] TootSweet product." Appellant's 3/20/09 Brief, p. 15 (underlining added). For the Board's reference, Appellant offers the following claim chart confirming that the cited evidence of record "establishes that Appellant's claims read on the advertised product." Board's Decision, p. 14.

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
<u>Claim 1</u>	
1. A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:	 <p data-bbox="523 845 899 912">p. 1: "TootSweet helps calm and soothe babies in distress and during painful procedures..."</p> <p data-bbox="523 918 840 942">p. 1: "For preemie and full-term babies"</p> <p data-bbox="523 949 878 1002">p. 2: "TootSweet has a two-year shelf life in un-opened containers."</p>





Appellant's Claims <sup>7</sup>	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
containers in a shipping container;	1oz cups with 12 ml 24% sucrose solution <u>Box of 40 [or] Case of 240 (6 boxes)</u> (underlining added)
shipping the shipping container to an intended site of usage of the solution;	p. 2: "Ordering Information... <u>Box of 40 [or] Case of 240 (6 boxes)</u> " (underlining added) p. 2: "[a]lways follow your hospital protocols for sucrose use."
opening an individual, single-use container of the solution prior to the planned medical procedure;	p. 1: "TootSweet helps calm and soothe babies in distress and during painful procedures..." p. 2: " <b>Instructions for Use</b> TootSweet has a two-year shelf life in un-opened containers. TootSweet is single patient use. TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping.... Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient."
administering a selected volume dose of the solution orally to the neonatal infant; and	p. 1: "For preemie and full-term babies" p. 2: " <b>Instructions for Use</b> ... Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient."
discarding any residual solution within the opened, individual, single-use container after the planned medical procedure.	Because TootSweet is "single patient use" (p. 2), TootSweet has a long shelf-life "in unopened containers" (p. 2), and the dose is "[j]ust a couple of drops" (p. 2) out of the "12 ml" (p. 2) of solution in the container, the

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
	advertisement inherently discloses "discarding any residual solution within the opened, individual, single-use container after the planned medical procedure."
<u>Claim 17</u>	
17. A method of administering a solution to a neonatal infant, comprising:	 <p data-bbox="501 742 864 853">     p. 1: "TootSweet helps calm and soothe babies in distress and during painful procedures..."      p. 1: "For preemie and full-term babies"      p. 2: "TootSweet has a two-year shelf life in un-opened containers."   </p>

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
<p>providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container;</p>	<p>p. 2: "PRODUCT SPECIFICATIONS: 1 oz cup containing 12 ml of 24% sucrose in purified water."</p> <p>p. 2: "TootSweet has a two-year shelf life in un-opened containers."</p> <p>p. 1: "Single patient use"</p> <p>p. 1: "Large cup ... (single patient use only)"</p> <p>p. 1: "Baby-appropriate preservatives prevent bacterial growth"</p> <p>p. 1: "Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration."</p>
<p>opening the container;</p>	

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
	
<p>withdrawing a selected dose of the solution from the opened container and administering the selected dose of the solution to the neonatal infant; and</p>	<p>p. 2: <b>Instructions for Use</b> TootSweet has a two-year shelf life in un-opened containers. TootSweet is single patient use. TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping.... Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient."</p>
<p>discarding any residual solution with the container.</p>	<p>Because TootSweet is "single patient use" (p. 2), TootSweet has a long shelf-life "in unopened containers" (p. 2), and the dose is "[j]ust a couple of drops" (p. 2) out of the "12 ml" (p. 2) of solution in the container, the advertisement inherently discloses "discarding any residual solution with the container."</p>
<p><b>Claim 23</b></p>	

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
<p>23. A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user, the packaged solution assembly comprising:</p>	 <p>p. 1: "TootSweet helps calm and soothe babies in distress and during painful procedures..."</p> <p>p. 1: "For preemie and full-term babies"</p> <p>p. 2: <b>Instructions for Use</b> TootSweet has a two-year shelf life in un-opened containers. ... TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping.... Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient."</p>

Appellant's Claims	Hawaii Medical's Advertised TootSweet <sup>TM</sup> Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
<p>a cup-shaped container having a width and a depth, the width being greater than the depth and defining a cavity therein opening to a mouth, the cavity further defining an inner surface, the cup-shaped container also includes a flange extending outwardly about the mouth, the flange includes a top surface, the container is constructed from a polymeric material;</p>	
<p>a volume of a solution comprising sucrose and water disposed within the cavity, the solution comprising approximately 24% sucrose and approximately 76% water; and</p>	<p>p. 2: "PRODUCT SPECIFICATIONS: 1 oz cup containing 12 ml of 24% sucrose in purified water. 0.022% methylparaben and 0.073% potassium sorbate as preservatives. Citric acid and dibasic sodium phosphate as buffers to adjust osmolarity."</p>
<p>a cover disposed over the mouth and sealing the solution within the cavity, the cover sealingly engaging at least a portion of the top surface of the flange, the cover further including a tab extending beyond the periphery of the flange such that the user can easily grasp and remove the cover.</p>	

Appellant's Claims	<p>Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)</p>
	<p>("LIFT" tab visible in lower right corner of photograph)</p>
<p><b><u>Claim 29</u></b></p> <p>29. A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user via an object, the packaged solution assembly comprising:</p>	 <p>p. 1: "TootSweet helps calm and soothe babies in distress and during painful procedures..."</p> <p>p. 1: "For preemie and full-term babies"</p> <p>p. 2: <b>Instructions for Use</b> TootSweet has a two-year shelf life in un-opened containers. ... TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping.... Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient."</p>



Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
<p><u><b>Claim 37</b></u></p> <p>37. A method of producing a packaged solution assembly for use in conjunction with a medical procedure on an infant, the method comprising the steps of:</p>	
<p>providing a cup-shaped container having a width and an depth, the width being sized to receive at least a portion of an object therein, the cup-shaped container defining a cavity therein opening to a mouth, the cup-shaped container further comprising a flange extending about the mouth of the cavity;</p>	

Appellant's Claims	Hawaii Medical's Advertised TootSweet™ Advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief)
mixing between approximately 10% to 50% sucrose with water to create a sucrose solution;	p. 2: "PRODUCT SPECIFICATIONS: 1 oz cup containing 12 ml of 24% sucrose in purified water."
transferring the sucrose solution into the cavity of the container; and	p. 2: "1 oz cup containing 12 ml of 24% sucrose in purified water"
sealing the container with a cover that is placed over the mouth and sealed with the flange of the container.	 <p data-bbox="523 779 902 845">p. 1: "Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration."</p> <p data-bbox="523 885 728 912">p. 1: "Two year shelf life"</p>

Appellant submits that the Board's Decision overlooked the evidence provided in Hawaii Medical's TootSweet advertisement (Exhibit D to Evidence Appendix X of Appellant's 3/20/09 Brief), which clearly "establishes that Appellant's [independent] claims read on the advertised product." Board's Decision, p. 14.

Because Appellant's evidence established that the competitor's advertised product reads on all of the pending independent claims, Appellant asks the Board to consider Appellant's compelling evidence that competitor Hawaii Medical showed great adulteration in its advertisement

for the exact features that distinguish the claimed invention from prior art “homemade” sugar solutions, which were mixed on site by a pharmacist. *See, e.g.*, Hawaii Medical’s TootSweet advertisement (Exhibit D to Evidence Appendix X of Appellant’s 3/20/09 Brief), p. 1 (“More economical and consistent than ‘homemade’ solutions”); *id.* (“easy to use”); *id.* (“Two-year shelf life”); *id.* (“Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration.”); *id.* (“Now there’s a safe, convenient way to deliver sucrose solution to your babies...”); Appellant’s 3/20/09 Brief, p. 15. Such adulation for the presently claimed invention clearly demonstrates that even Appellant’s competitor recognized the uniqueness, marketability, and value of the presently claimed invention. Such adulation by an unbiased and independent third party is “a strong indication of the non-obviousness of [the] invention.” *Libbey-Owens-Ford Co. v. BOC Group Inc.*, 655 F. Supp. 897, 914, 4 USPQ.2d (BNA) 1097, 1109 (D. N.J. 1987). Appellant asks the Board to reverse the pending obviousness rejection of all claims for at least this reason.

### **III. The Board’s Decision Overlooked Appellant’s Proven Nexus Between The Commercial Success Of SWEET-EASE™ And SWEET-EASE™’s use of the Claimed Invention**

Pages 15-18 of Appellants’ March 20, 2009 Brief established that Appellant’s SWEET-EASE™ product was commercially successful and embodied the claimed invention, and that there was a nexus between that commercial success and SWEET-EASE’s incorporation of the claimed invention. The Board’s Decision rejected Appellant’s nexus proof, asserting that “Appellant’s evidence fails to establish that the success was due to the merits of the claimed invention beyond what was readily available in the prior art, e.g., conventional formulations of sweet solutions.” Board’s Decision, pp. 13-14. To the contrary, Appellant’s evidence established a direct nexus between the success and the difference between the claimed invention and the prior art (e.g., the use of a sealed ready-to-use container of sucrose solution, as opposed to the prior art home-made sucrose solutions made by pharmacists just prior to use). The declaration of Catherine Bush (Exhibit B of Appendix X of Appellant’s March 20, 2009 Brief) (“Bush Declaration”) established her reasoned belief that “these extraordinary sales results are because the SWEET-EASE™ product [i.e., claimed invention] provides a convenient, aseptically packaged container.” Bush Declaration, ¶ 5. The declarations of Dr. Don Granger, M.D. (Exhibit C of Appendix X of Appellant’s March 20, 2009 Brief) (“Granger Declaration”), Dr.

Neal Guttenberg, M.D. (Exhibit C of Appendix X of Appellant's March 20, 2009 Brief) ("Guttenberg Declaration"), and Dr. David Yohannan, M.D. (Exhibit C of Appendix X of Appellant's March 20, 2009 Brief) ("Yohannan Declaration") further establish that the claimed self-contained containers of sucrose solution filled a need that had not been satisfied by the prior art home-made preparation of a sucrose solution by a pharmacist. *See* Granger Declaration, ¶¶ 3-7; Guttenberg Declaration, ¶¶ 3-7; Yohannan Declaration, ¶¶ 3-7.

Appellant's competitor's above discussed adulteration for the claimed invention in its own advertising further proves the nexus between the commercial success and the claimed invention. *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ.2d (BNA) 1378, 1384 (Fed. Cir. 1997) ("The prominence of the patented technology in [the infringer's] advertising creates an inference that links the Gambro invention to this [commercial] success," thereby proving the required nexus.); *see also* *Bose Corp. v. JBL, Inc.*, 112 F. Supp.2d 138, 156 (D. Mass. 2000) ("[An infringer's] adulteration of the [product] is the best evidence of the extent of its commercial success.").

This compelling evidence demonstrates a nexus between the commercial success and the claimed invention, which objectively proves the non-obviousness of the claimed invention. Appellant asks the Board to reverse the pending obviousness rejection of all claims for at least this reason.

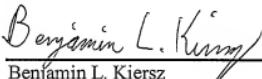
#### **IV. CONCLUSION**

For at least the above reasons, as well as the additional reasons provided in Applicant's March 20, 2009 Appeal Brief, Appellant respectfully requests the rehearing of this appeal and reversal of the pending rejections of claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39.

Having overcome all objections and rejections, Appellant therefore respectfully requests allowance of the present application.

Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,  
PILLSBURY WINTHROP SHAW PITTMAN LLP



Benjamin L. Kiersz  
Reg. No. 51,875

For: Timothy Nathan  
Registration No. 44,256

**Mail all correspondence to:**

Timothy Nathan, Esq.  
Philips Intellectual Property & Standards  
PO Box 3001  
Briarcliff Manor, NY 10510-8001, USA  
Phone: (724) 387-4435  
e-mail: timothy.nathan@philips.com